

REMARKS

This amendment responds to the Office Action mailed February 22, 2008. Claims 93-97 and 104-107 were pending and under consideration. In the instant amendment, claims 93 and 106 have been amended and claims 95, 96, 104, and 107 have been canceled without prejudice to Applicants' right to pursue the canceled subject matter in this application or one or more related continuation, divisional, or continuation-in-part applications. After entry of the instant amendment, claims 93, 94, 97, 105 and 106 are pending and under consideration in the instant application.

I. AMENDMENTS TO THE CLAIMS

Claims 93 and 106 have been amended. Support for amended Claim 93 can be found, for example, in the specification at page 12, line 27 to page 13, line 13, and at page 24, line 26 through page 25, line 8; and in claims 25-28, 31, 33, 61, 63, and 93 as originally filed. Claim 106 has been amended to eliminate a redundant limitation. Applicants respectfully submit that these amendments are fully supported by the application as filed and therefore do not introduce any new matter. Accordingly, entry and consideration of this amendment are respectfully requested under 37 C.F.R. § 1.111.

II. THE REJECTION OF CLAIMS 93-97 and 105-107 UNDER 35 U.S.C. § 102(b)

Claims 93-97 and 105-107 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 99/67427A1 by Petropoulos *et al.* ("Petropoulos *et al.*"). Applicants respectfully submit that the rejection is moot with respect to claims 95, 96, 104, and 107 in view of the cancellation of such claims, and traverse with respect to the remaining pending claims.

Claims 93, 94, 97, 105 and 106 recite a method of determining whether an HIV infecting a patient has reduced non-nucleoside reverse transcriptase inhibitor ("NNRTI") susceptibility **and** increased replication stimulated by an anti-viral drug comprising: detecting, in a biological sample from the HIV-infected patient, the presence of a mutation at particular combinations of a nucleic acid encoding HIV reverse transcriptase, wherein the presence of said mutations is correlated with a decrease in NNRTI susceptibility or with a drug-dependant stimulation of viral replication, and determining whether the HIV has reduced NNRTI susceptibility and increased replication stimulated by an antiviral drug.

Applicants respectfully submit that Petropoulos *et al.* does not anticipate claims 93, 94, 97, 105 and 106 of the present invention because it does not teach, expressly or

inherently, each and every element of claims 93, 94, 97, 105 and 106. Specifically, Petropoulos *et al.* does not teach that the mutations recited by claims 93, 94, 97, 105 and 106 correlate with a drug-dependant stimulation of viral replication. The PTO argues that Petropoulos teaches a method where the recited mutations are detected, and thus inherently teaches a method where drug dependent stimulation is determined. However, the doctrine of inherent anticipation requires that each and every time the method described in the prior art is performed, the claimed method is actually practiced. *See, for example, Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 USPQ2d 1597 (Fed. Cir. 2002). Thus, for Petropoulos *et al.* to inherently anticipate the instantly claimed invention, performing the methods of Petropoulos *et al.* are performed, results each and every time in a determination of drug-dependent stimulation of replication

However, nowhere does Petropoulos *et al.*, either impliedly or expressly, disclose a correlation between the mutations recited by the instant claims and determination of drug-dependent stimulation of replication. Rather, Petropoulos *et al.* focuses on the effects of the mutations on drug resistance. Merely determining drug resistance, as disclosed by Petropoulos *et al.*, in no way allows one of ordinary skill in the art to determine drug-dependent stimulation of viral replication. Put another way, there is no way for the skilled artisan, performing the method of Petropoulos *et al.*, to achieve the results accomplished by the instantly claimed methods because Petropoulos *et al.* fails to disclose the correlation between the mutations and the effect. As such, no matter how many times the methods of Petropoulos *et al.* are performed, they cannot accomplish the results achieved by the instantly-claimed methods.

As such, Petropoulos *et al.* does not teach each and every element of the claimed invention and therefore does not anticipate claims 93, 94, 97, 105 and 106. Accordingly, Applicants respectfully request that the rejection of claims 93-97 and 105-107 under 35 U.S.C. § 102(b) be withdrawn.

III. THE REJECTION OF CLAIMS 93-97 and 105-107 UNDER 35 U.S.C. § 112

FIRST PARAGRAPH

Claims 93-97 and 105-107 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the application as filed. Without acquiescing to the propriety of the rejection, and solely to expedite prosecution of the claims, claim 93 has been amended to recite subject matter clearly enabled by the specification. In particular, Example 13 clearly indicates that the combination of mutations V245T and I135T, V245E, K103N,

and I135T, and V245T, K103N, and I135T results in drug-dependent stimulation of replication. Accordingly, Applicants believe the enablement rejection under 35 U.S.C. § 112, first paragraph, is moot in view of the amendments to the claims and therefore respectfully request its withdrawal.

CONCLUSION

Applicants believe that the claims of the instant application meet all of the conditions for patentability and are in condition for allowance. Accordingly, an early indication of the same is respectfully requested.

No fees are believed to be due with this response other than those associated with the extension of time. However, pursuant to 37 C.F.R. §1.136 (a)(3), the Commissioner is authorized to charge all required fees, or credit any overpayment, to Jones Day Deposit Account No. 50-3013 (949677-999065).

Date: August 22, 2008

Respectfully submitted,



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